



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,160	06/14/2005	Thomas Gradel	190-89	2690
2746	7590	09/26/2007		
WILLIAM H. EILBERG THREE BALA PLAZA SUITE 501 WEST BALA CYNWYD, PA 19004			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,160

Applicant(s)

GRADEL ET AL.

Examiner

James L. Swiger

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 0207.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to because applicant should amend the specification to claim foreign priority. Copies of appropriate documents and the application data sheet have been received on 8/20/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-19, 21-23 and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (Reference Pub. No.: 2002/0068976 A1).

Jackson discloses an intervertebral implant (1) comprising a solid biocompatible material implant body (5) having a tubular general structure delimited by an upper wall (15) and a lower wall (16), two opposite lateral walls (see Figure 1 below) that are plane and slightly divergent toward the front, and a posterior wall (17) with a threaded axial hole (50), with a single interior cavity (see Figure 1 below; paragraph 0036) providing communication between orifices provided in the upper wall (15) and the lower wall (16),

Art Unit: 3733

wherein: the upper (15) and lower (16) wall each comprise a respective single large upper or lower orifice (45, 46), an interchangeable compression plug (6, 7, 8, 9; paragraph 0034); the interior cavity is closed toward the front by an anterior wall (see Figure 1 below), the width of the implant (1) defined by the lateral walls is less than its height defined by the upper and lower wall. It is noted that Jackson's implant could also be cylindrical in shape (paragraph 0011), therefore allowing the width of the implant to be less than its height. Because of the upper and lower orifice, the interior cavity is open over the whole of its width between the lateral walls and over the whole of its length between the posterior and anterior wall (see Figure 1 below).

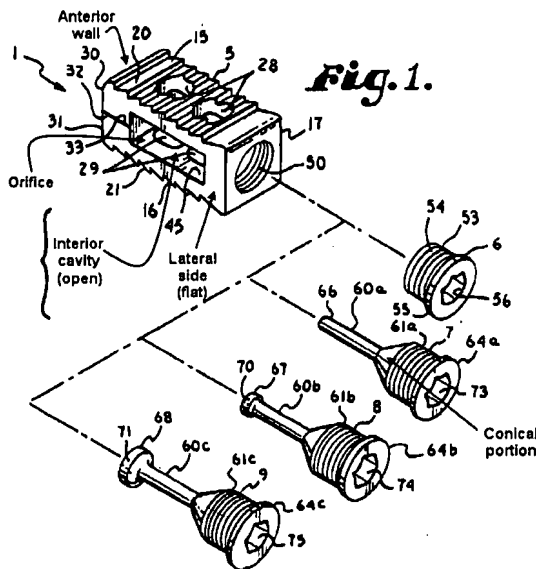
The interchangeable compression plug (6, 7, 8, 9) comprises a conical interior end portion (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) and the threaded axial hole (50) that receives it have a diameter substantially equal to the width of the interior cavity in the vicinity of the posterior wall (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) has a length such that, at the end of screwing it into the threaded axial hole (50) that receives it, its interior end portion penetrates the interior cavity to a distance of at least one quarter of the length of said interior cavity (paragraph 0041-0043). The implant (1) has at least two interchangeable compression plugs (6, 7, 8, 9; paragraph 0034) having different lengths (paragraph 0041). The anterior wall includes an eccentric threaded hole of smaller diameter (paragraph 0038). The upper and lower larger wall include annular toothed anti-expulsion ribs (paragraph 0037). The interchangeable compression plug is made of titanium (paragraph 0011). The upper (15) and lower wall (16) are each of conical

Art Unit: 3733

general shape and the upper and lower orifice are each bordered at their anterior and posterior ends by a flat perpendicular to the lateral walls (see Figure 1 below).

It is noted that Jackson's invention is used between a pair of adjacent vertebrae in order to provide stabilization between the vertebrae that has been destabilized due to injury. Also, the "expandible member" disclosed by Jackson is capable of compressing the implant into the vertebrae and therefore stabilizing the vertebrae. It is further noted that Jackson discloses that in some circumstances different members of windows may be provided in the upper and lower walls. Therefore, Jackson's implant could have a single orifice instead of two smaller orifices.

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Jackson (i.e. "adapted to be fitted by screwing it into the threaded axial hole in the posterior wall"), which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Schläpfer et al. (Reference U.S. Patent "6,059,829").

Jackson discloses the claimed invention except for the upper and lower wall being convex and slightly divergent toward the front and the posterior wall of the implant including an external diametral groove. Schläpfer et al. (herein Schläpfer) teaches to provide the upper and lower wall being convex and slightly divergent toward the front

Art Unit: 3733

(col. 2, lines 6-23) in order for the implant to have an overall lens shape. Schläpfer further teaches to provide the posterior wall of the implant including an external diametral groove (col. 3, lines 38-42) in order to grip the implant by an instrument and it is possible to apply a rotational torque via the instrument directly to the implant. It would have been obvious to one skill in the art at the time the invention was made to construct the device of Jackson having the upper and lower wall being convex and slightly divergent toward the front and the posterior wall of the implant including an external diametral groove, in view of Schläpfer, in order for the implant to have an overall lens shape, in terms of the upper and lower wall being convex, and in order to grip the implant by an instrument and it is possible to apply a rotational torque via the instrument directly to the implant.

Claims 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Schläpfer et al. (Reference U.S. Patent "6,059,829") and further in view of Brantigan (Reference U.S. Patent "5,425,772").

The combination of Jackson and Schläpfer discloses the claimed invention except for the implant body made of a PEEK type polymer and the implant comprising titanium marker in the implant body away from the interchangeable compression plug. Brantigan teaches to provide an implant made of a PEEK type polymer (col. 3, lines 47-57) in order to reduce the affects of the compression and for promoting better bone fusion. Brantigan further teaches to provide the titanium markers in the implant body in order to visualization of postoperative bone healing. It would have been obvious to one

skilled in the art at the time the invention was made to construct the device of the combination of Jackson as modified by Schlöpfer, having the implant body made of a PEEK type polymer and having titanium marker, in view of Brantigan, in order to reduce the affects of the compression, promote bone growth and for visualization of postoperative bone healing.

Response to Arguments

Applicant's arguments filed 8/20/2007 have been fully considered but they are not persuasive. It is noted that the intervertebral implant as disclosed by Jackson would have both a longitudinal axis along its centerline, and also a transverse axis. As noted the implant also has a height, which, in use of the implant is capable of varying (compares Figs. 5, 6, 13) showing that the height may vary in use. It is further noted that when the device is expanded, creating a greater height as mentioned above, the width would be less than the height (since the implant has a generally square shape when it is in a neutral position).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


Art Unit: 3733

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 9/22/07

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER